November 18, 2002

K021501

510(K) SUMMARY: V.A.C. Instillamat Device

DEC 0 2 2002

I. Name of Device: **V.A.C.® Instillamat Device**

II. Classification Name: **Powered Suction Pump**
21 CFR 878.4780

III. 510(k) Applicant:

Kinetic Concepts, Inc. (KCI)
8023 Vantage Drive
San Antonio, TX 78265-8508
Contact: Judith Harbour 1-800-275-4524

IV. Substantial Equivalence: **V.A.C. Plus**
510(k) No.K992448
Ambulatory V.A.C.
510(k) No.K971548

V. Description of Device

The V.A.C. Instillamat device is a modified V.A.C. device manufactured by Kinetic Concepts Inc. The V.A.C. Instillamat device combines technologies and features of the V.A.C. Plus device previously cleared by the FDA in 1999 [510(k) No. K992448] and the Ambulatory V.A.C. device previously cleared by the FDA in 1997 [510(k) No. K971548] with the additional modifications to provide a controlled delivery system for applying secondary wound treatments to a wound.

VI. Indications for Use

The V.A.C. Instillamat device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

VII. Substantial Equivalence

The V.A.C. Instillamat device has essentially the same technologies and features as the previously cleared predicate devices and has been independently tested and successfully approved to the following medical safety standards:

- UL2601-1, The Standard for Safety of Medical Electrical Equipment, 1st Edition 1994
- IEC 60601-1-1, Medical Electrical Equipment - Part 1: General Requirements for Safety; 1. Collateral Standard: Safety Requirements for Medical Electrical Systems
- IEC 60601-1-2, Medical Electrical Equipment - Part 1: General Requirements for Safety; 2. Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-4, Medical Electrical Equipment – Part 1; General Requirements for Safety; 4. Collateral Standard: Programmable Electrical Medical Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

KCI USA, Inc.
% Ms. Christy Oviatt
6203 Farinon Drive
San Antonio, Texas 78230

Re: K021501
Trade/Device Name: Vacuum Assisted Closure Instillamat
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: August 31, 2002
Received: September 2, 2002

Dear Ms. Oviatt:

This letter corrects our substantially equivalent letter of December 2, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021501

510(k) Number (if known): K021501

Device Name: **V.A.C. Instillamat®**

Indications For Use:

The V.A.C. Instillamat device is indicated for patients who would benefit from vacuum assisted drainage and controlled delivery of topical wound treatment solutions and suspensions over the wound bed.

The V.A.C. is intended for patients with chronic, acute, traumatic, subacute and dehisced wounds, diabetic ulcers, pressure ulcers, flaps and grafts.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-The-Counter Use ____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K021501